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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FILIPPO BELARDELLI, STEFANO MARIA SANTINI, STEFANIA PARLATO, TIZIANA DI PUCCHIO, MARIANTONIA LOGOZZI, CATERINA LAPENTA, MARIA FERRANTINI, LAURA SANTODONATO, and GUIUSEPPINA D'AGOSTINO

Appeal 2008-1869[1]
Application 09/845,042
Technology Center 1600

Decided: August 14, 2008

Before DONALD E. ADAMS, MELANIE McCOLLUM, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 54, 55, 57, 58, 61-63, 66, 67, and 69-81. Pending claims 82 and 83 have been "withdrawn from consideration" (App. Br. 1). We have jurisdiction under 35 U.S.C.

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[1] Oral Hearing held July 10, 2008.

§ 6(b).

INTRODUCTION

The claims are directed to a process for deriving dendritic cells from mononuclear cells in culture (claims 54, 55, 57, 58, 61, and 62); a method for the ex vivo derivation of dendritic cells from mononuclear cells within 3 days of culture (claims 63, 66, and 67); a method for the ex vivo derivation of dendritic cells from mononuclear cells (claims 69-71); a process for producing dendritic cells from monouclear cells (claims 72-81). Claims 63 and 72 are illustrative:

63. A method for the ex vivo derivation of dendritic cells from mononuclear cells within 3 days of culture, wherein said mononuclear cells are peripheral blood mononuclear cells (PBMC) or CD14+ monocytes, comprising culturing type I IFN for a maximum of 3 days with said mononuclear cells from the beginning of said culture at a concentration range of 500 to 10,000 IU/ml, in the presence of GM-CSF at a concentration in a range of 500-1,000 IU/ml, and in the absence of IL-4.

72. A process for producing dendritic cells from mononuclear cells wherein said mononuclear cells are peripheral blood mononuclear cells (PBMC) or CD14+ monocytes, comprising culturing said mononuclear cells for a maximum of 3 days with type I interferon (IFN) at a concentration in the range of 400-10,000 IU/ml in the presence of GM-CSF at a concentration in a range of 250-1,000 IU/ml, and wherein said dendritic cells express higher levels of CD83 and CD25 antigens as compared to mononuclear cells or monocytes that have been cultured within 3 days of treatment with GM-CSF and IL-4.

The Examiner does not rely on prior art to support the rejection of record.

The rejection as presented by the Examiner is as follows:

Claims 54, 55, 57, 58, 61-63, 66, 67, and 69-81 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph, as introducing new matter into the claims.

We reverse.

DISCUSSION

According to the Examiner, Appellants' Specification fails to provide written descriptive support for the claimed invention as it relates to the phrases "in the absence of IL-4;" in the absence of added IL-4;" "for a maximum of 3 days;" "within 3 days;" collecting cells within 3 days;" "a concentration range of 500-10,000 IU/ml" of IFN; "a concentration range of 500-1000 IU/ml" of GM-CSF (Ans. 4 (emphasis removed)). We take each in turn.

In the absence of IL-4 or in the absence of added IL-4:

The Examiner concedes that Appellants have disclosed experiments that were performed without the use of IL-4 (Ans. 5). Appellants assert that "pages 16-17 [of their Specification provides a] detailed description of the culturing conditions for the IFN-DCs [and] omits any mention of IL-4, confirming its absence" (App. Br. 6). More specifically, Appellants assert that "pages 19-39 of the[ir] specification [discloses] dendritic cells according to the invention, prepared in the presence of IFN and GM-CSF ('IFN-DCs') . . . [and] compare[s] and contrast[s] [these IFN-DCs] with dendritic cells prepared in the presence of interleukin 4 (IL-4) and GM-CSF ('IL-4-DCs')" (*id.*; *see also* Reply Br. 3). Accordingly, Appellants assert that the performance of the claimed method "'in the absence of IL-4' is well-

supported by the disclosure" (*id.*). We agree. As there is a working example of experiments performed without IL-4, it is clear that Appellants contemplated such conditions for the processes encompassed by the claims.

We recognize the Examiner's assertion that Appellants' disclosure fails to support the "generic method of the instant claims that . . . specifically excludes the use of IL-4 in all methods encompassed by the instant claims" (Ans. 5). While less than clear, it appears that the Examiner may also be concerned that Appellants' Specification does not provide an enabling description of the claimed invention. We note, however, that the Examiner has not presented an enablement rejection on this record. Accordingly, we take no position on the merits of the Examiner's assertion as it may apply to the enablement provision of 35 U.S.C. § 112, first paragraph.

In sum, Appellants' Specification has written descriptive support for culturing mononuclear cells in the absence of IL-4 and in the absence of added IL-4. Accordingly, we are not persuaded that the addition of this limitation to the claims represents new matter.

For a maximum of 3 days, within 3 days, collecting cells within 3 days:

According to Appellants, their Specification:

> [E]xplicitly [teaches] at page, 5, lines 28-32 that the process is preferably carried out '<u>within three days of culture</u>' and the three-day culture is mentioned repeatedly throughout the specification, for example at page 9, lines 29 and 32-33; [p]age 10, lines 3 and 20; page 11, line 20; page 12, lines 1, 7, 22 and 29-30; page 14, line 1; page 15, lines 12-13; page 18, lines 16-18 and 19-20; page 26, lines 6-8 and page 28, line 30.

(App. Br. 7.) According to Appellants "[t]hese passages clearly support the recitations of 'for a maximum of three days,' 'collecting cells within three

days,' and 'within three days' . . . that appear in the claims on appeal" (*id.*). We agree.

We are not persuaded by the Examiner's assertion that Appellants have introduced new matter into the claims because the phrase "within 3 days" appears only in the Summary of the Invention section of Appellants' Specification (Ans. 5). This section of Appellants' disclosure states that "[a] second advantage of the process of the invention is that it provides a particularly rapid procedure for DC production which can be carried out in a brief period of time (within three days of culture)" (Spec. 5: 19-22). Appellants' Specification discloses that "the process of the invention is preferably carried out within three days of culture" (Spec. 5: 28-29). Appellants' description of their Figure 1 expressly teaches a comparison of cells treated for "three days" with IFNαn and GM-CSF to those treated for "three days" with IL-4 and GM-CSF (Spec. 9: 27-33; *See also*, *inter alia*, Appellants' description of their Figure 5 (Spec. 11: 18-20)).

We disagree with the Examiner's assertion that "the time period for recovery of cells is 'between day 2 and day 3' [as Appellants disclose at page 18, lines 19 and 20 of their Specification] . . . is not commensurate in scope with a time period of 'a maximum of 3 days', which would obviously include day 1" (Ans. 5-6). The section of Appellants' Specification relied upon by the Examiner states "[p]referably, the cells recovered between day 2 and day 3 are used directly or purified . . ." (Spec. 18: 19-20). Alas, the Examiner's conclusion is based on a disclosed preference, instead of a fair reading of Appellants' entire Specification in context.

In context, Appellants' Specification teaches a method/process of culturing cells that can be performed within 3 days of culture (Spec. 5: 19-

22, 28-29, and originally filed claim 2). Within 3 days, includes 1 day. Further, the Examiner admits that Appellants' Specification teaches "a culture period of 3 days" (Ans. 5), which establishes support for the upper limit of 3 days. Accordingly, we disagree with the Examiner's assertion that "neither the terms 'for a maximum of 3 days' or 'within 3 days' are adequately supported by the instant Specification" (Ans. 6). For the foregoing reasons we also disagree with the Examiner's assertion that the phrase "collecting cells within 3 days" does not have written descriptive support in Appellants' Specification.

A concentration range of 500-10,000 IU/ml of IFN:

> Appellants' Specification discloses that
>
> IFN shall generally be present in the culture medium at a final concentration greater than 100 IU /ml. Preferred embodiments in this connection are, however the ones wherein type I IFN is present in a concentration comprised in a range of 100-10,000 IU /ml, or more preferably in a range of 400-10,000 IU /ml, or 500-2,000 IU /ml, particularly 1,000 IU /ml.

(Spec. 6: 6-12.)

According to Appellants, "[t]he explicit disclosure of [these] preferred ranges . . . unquestionably supports the recited range of 500-10,000 IU/ml. See, e.g., *In re Wertheim et al*, 541 F.2d 257 . . . (CCPA 1976)" (App. Br. 8; Reply Br. 2-3). We agree.

A concentration range of 500-1,000 IU/ml" of GM-CSF:

Appellants' Specification discloses that "GM-CSF is used preferably at a concentration in a range of 250-1,000 U/ml" (Spec. 5: 33-34); and the use of "500 U/ml of GM-CSF" (Spec. 10: 19-20).

According to Appellants "[t]he *Wertheim* case identified above likewise compels the conclusion that this range is not new matter" (App. Br. 8). We agree.

For the foregoing reasons, we reverse the new matter rejection of claims 54, 55, 57, 58, 61-63, 66, 67, and 69-81 under the written description provision of 35 U.S.C. § 112, first paragraph.

CONCLUSION

In summary, we reverse the rejection of record.

REVERSED

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